

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a physician's prescription only

Tivicay 10 mg

Tivicay 25 mg

Tivicay 50 mg

Film-coated tablets

Each tablet contains:

Tivicay 10 mg: **dolutegravir (as sodium) 10 mg**

Tivicay 25 mg: **dolutegravir (as sodium) 25 mg**

Tivicay 50 mg: **dolutegravir (as sodium) 50 mg**

For the list of inactive and allergenic ingredients in the preparation, see section 2 - "Important information about some of the ingredients in this medicine" and section 6 - "Additional information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you (or your child, if they are the patient). Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Tivicay is used as combination therapy (in combination with other antiretroviral medicines) to treat **HIV (human immunodeficiency virus) infection** in adults, adolescents and children from the age of 6 years and weighing at least 14 kg.

Tivicay does not cure the HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. As a result, it also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

Not everyone responds to treatment with Tivicay in the same way. Your physician will monitor the effectiveness of your treatment.

Tivicay treatment is always in combination with other antiretroviral medicines (*combination therapy*). To control the HIV infection, and to prevent the illness from getting worse, you must continue taking all your medicines, unless your

physician tells you otherwise.

Therapeutic group

Tivicay contains the active ingredient dolutegravir. This medicine belongs to a group of antiretroviral medicines called *integrase inhibitors (INIs)*.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- if you (or your child, if they are the patient) are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine (detailed in section 6).
 - if you (or your child) are taking another medicine called fampridine (also known as dalfampridine – used to treat multiple sclerosis).
- **Tell the physician** if you think any of these apply to you (or your child).

Special warnings regarding use of the medicine

Look out for important symptoms

Some people taking medicines for HIV infection develop other problems, which can be serious. These include:

- symptoms of infections and inflammation
- joint pain, stiffness and bone problems

You need to know about important signs and symptoms to look out for while you (or your child, if they are the patient) are taking Tivicay.

→ **Read the information in section 4 of this leaflet.**

Children and adolescents

Do not give this medicine to children under the age of 6, weighing less than 14 kg or with HIV infection that is resistant to other medicines similar to Tivicay. The safety and efficacy of the use of Tivicay film-coated tablets in children under the age of 6 or weighing less than 14 kg have not been proven.

It is important to schedule **planned physician's appointments** for children (for more information, see "Use in children and adolescents" in section 3).

Drug interactions

If you (or your child) are taking, have recently taken or are planning (or your child) to take other medicines, including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist.

Do not take Tivicay with the following medicine:

- Fampridine (also known as dalfampridine), used to treat **multiple sclerosis**.

Some medicines can affect how Tivicay works, or increase the risk of side effects. Tivicay can also affect how other medicines work.

Tell your physician if you (or your child) are taking any of the medicines *from the following list*:

- metformin, to treat **diabetes**.

- medicines called **antacids**, to treat **indigestion and heartburn**. **Do not take an antacid** during the 6 hours before taking Tivicay, or for at least 2 hours after taking it (*see also section 3*).
 - supplements or multivitamins containing calcium, iron or magnesium. **If you take Tivicay with food**, you can take supplements or multivitamins containing calcium, iron or magnesium at the same time as Tivicay. **If you do not take Tivicay with food, do not take a supplement or multivitamin containing calcium, iron or magnesium** during the 6 hours before you take Tivicay, or for at least 2 hours after you take it (*see also Section 3*).
 - etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir, to treat **HIV infection**.
 - rifampicin, to treat tuberculosis (TB) and other **bacterial infections**.
 - phenytoin and phenobarbital, to treat **epilepsy**.
 - oxcarbazepine and carbamazepine, to treat **epilepsy** or **bipolar disorder**.
 - **St. John's wort** (*Hypericum perforatum*), a herbal remedy to treat **depression**.
- **Tell your physician** if you (or your child) are taking any of these medicines. Your physician may decide to adjust your dose or that you need extra checkups.

Use of the medicine and food

See section 3 "How should you use the medicine".

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant, or if you are planning a pregnancy:

- **Consult with your physician** about the risks and benefits of taking Tivicay. Inform the physician immediately if you become pregnant or are planning to become pregnant. Your physician will review your treatment. Do not stop taking Tivicay without consulting your physician, as this may harm you and your unborn child.

Breast-feeding

Breast-feeding is **not recommended** in women living with HIV because HIV infection can be passed on to the baby via breast milk.

A small amount of the ingredients of Tivicay can pass into your breast milk.

If you are breast-feeding, or thinking about breast-feeding, you should **consult with your physician as soon as possible**.

Driving and using machines

Tivicay can cause dizziness and other side effects that make you less alert.

- **Do not drive or operate machinery** unless you are certain that you are not affected.

Important information about some of the ingredients in this medicine

Tivicay contains less than 1 mmol sodium (23 mg) per tablet, that is to say

is essentially 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or the pharmacist if you are unsure about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the physician only.

The usual dosage is generally:

For adults

- 50 mg, **once a day**.
- If you are taking **certain other medicines** (e.g., efavirenz, nevirapine, tipranavir, ritonavir or rifampicin), the dosage is 50 mg, **twice a day**.
- **For the treatment of HIV that is resistant** to other medicines similar to Tivicay (from the integrase class), the usual dose is 50 mg, **twice a day**.

For adolescents aged 12 years and above, to less than 18 years, and weighing at least 20 kg

- **For the treatment of HIV without resistance** to other medicines from the integrase class, the dose is 50 mg **once daily**, or 25 mg **twice daily**.
- **For the treatment of HIV resistant** to other medicines similar to Tivicay (from the integrase class), there are insufficient data to recommend a dose in adolescents.

For children aged 6 years and above, to less than 12 years, and weighing at least 14 kg

- **For the treatment of HIV-1 without resistance** to other medicines from the integrase class, the dose will be determined according to the table below:

Body weight (kg)	Dose
14 to less than 20	40 mg once daily
20 or greater	50 mg once daily

If required, the dose may be divided equally into 2 doses, with one dose taken in the morning and one dose taken in the evening (see table below) :

Body weight (kg)	Dose
14 to less than 20	20 mg twice daily
20 or greater	25 mg twice daily

- **For the treatment of HIV resistant** to other medicines similar to Tivicay (from the integrase class), there are insufficient data to recommend a dose in children.

The physician will decide on the correct dosage for you and your child.

Swallow the tablet/s with some liquid.

Tivicay can be taken with or without food. When Tivicay is taken twice a day,

your physician may advise you to take it with food.

There is no information regarding crushing/halving/chewing.

Tivicay is also available as **dispersible tablets**. Film-coated tablets and dispersible tablets are not the same; therefore, **do not switch** between film-coated tablets and dispersible tablets without first talking to your physician.

Use in children and adolescents

Children's dose of Tivicay needs to be adjusted as they get older or gain weight.

→ It is important therefore to schedule **planned physician's appointments** for children.

In order to reduce the risk of choking, **children must swallow each tablet separately.**

Tivicay should not be used in children and adolescents with **HIV infection that is resistant** to other medicines similar to Tivicay (from the integrase class).

Do not exceed the recommended dose

Antacid medicines

Antacids, to treat **indigestion and heartburn**, can prevent Tivicay from being absorbed into your body and make it less effective.

Do not take an antacid during the 6 hours before taking Tivicay, or for at least 2 hours after taking it. Other acid-lowering medicines like ranitidine and omeprazole can be taken at the same time as Tivicay.

→ Refer to your physician for further advice on taking acid-lowering medicines with Tivicay.

Supplements or multivitamins containing calcium, iron or magnesium

Supplements or multivitamins containing calcium, iron or magnesium can stop Tivicay being absorbed into your body and make it less effective.

If you take Tivicay with food, you can take supplements or multivitamins containing calcium, iron or magnesium at the same time as Tivicay. **If you do not take Tivicay with food, do not take a supplement or multivitamin containing calcium, iron or magnesium** during the 6 hours before you take Tivicay, or for at least 2 hours after you take it.

→ Refer to your physician for further advice on taking supplements or multivitamins containing calcium, iron or magnesium with Tivicay.

If you have accidentally taken a higher dosage

If you (or your child) have accidentally taken too many tablets of Tivicay, **refer to your physician or pharmacist for advice.** If possible, show them the Tivicay package. If a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine

If you (or your child) miss a dose, take it as soon as you remember. But if your next dose is due within 4 hours, skip the dose you missed and take the next

one at the usual time. Then continue your treatment as before.

→ **Do not take a double dose** to make up for a missed dose.

Do not stop taking Tivicay without consulting with your physician.

Adhere to the treatment regimen as recommended by the physician. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the physician.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Tivicay may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Allergic reactions

These are uncommon in people taking Tivicay. The signs include:

- skin rash
- a high temperature (*fever*)
- lack of energy (*fatigue*)
- swelling, sometimes of the mouth or face (*angioedema*), causing difficulty in breathing
- muscle or joint aches.

→ **Refer to a physician straight away.** Your physician may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking Tivicay.

Very common side effects

May occur in **more than 1 in 10 people**:

- headache
- diarrhoea
- nausea.

Common side effects

May occur in **up to 1 in 10 people**:

- rash
- itching
- vomiting
- stomach pain (*abdominal pain*)
- stomach (*abdominal*) discomfort
- weight gain
- insomnia
- dizziness
- abnormal dreams

- depression (feelings of deep sadness and lack of self-esteem)
- anxiety
- lack of energy (*fatigue*)
- wind (*flatulence*)
- increase in the level of liver enzymes
- increase in the level of enzymes produced in the muscles (*creatine phosphokinase*).

Uncommon side effects

May occur in **up to 1 in 100 people**:

- inflammation of the liver (*hepatitis*)
- suicide attempt*
- suicidal thoughts*
- panic attack
- joint pain
- muscle pain.

* Mainly in patients who have had depression or mental health problems in the past

Rare side effects

May occur in **up to 1 in 1,000 people**:

- liver failure (signs may include yellowing of the skin and the whites of the eyes, or unusually dark urine)
 - increase in blood bilirubin level (liver function test)
 - suicide (particularly in patients who have had depression or mental health problems before)
- **Tell your physician immediately** if you experience any mental health problems (see also other mental health problems above).

Symptoms of infection and inflammation

People with advanced HIV infection (AIDS) have a weak immune system, and are more likely to develop serious infections (*opportunistic infections*). Such infections may have been “silent” and were not detected by the weak immune system before treatment was started. After starting treatment, the immune system becomes stronger, and may attack the infections, which can cause symptoms of infection or inflammation. The symptoms usually include **fever**, as well as some of the following:

- headache
- stomach ache
- breathing difficulties

In rare cases, as the immune system becomes stronger, it can also attack healthy body tissue (*autoimmune disorders*). The symptoms of autoimmune disorders may develop many months after you start taking medicine to treat your HIV infection. The symptoms may include:

- palpitations (rapid or irregular heartbeat) or tremor

- hyperactivity (excessive restlessness and movement)
- weakness beginning in the hands and feet and moving up towards the trunk of the body.

If you (or your child) develop any symptoms of infection and inflammation or if you notice any of the symptoms above:

→ **Refer to your physician immediately.** Do not take other medicines for the infection without your physician's advice.

Joint pain, stiffness and bone problems

Some people taking combination therapy for HIV develop a condition called *osteonecrosis* (bone necrosis). In this condition, parts of the bone tissue die due to reduced blood supply to the bone. People may be more likely to develop this condition:

- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune system is very weak
- if they are overweight.

Signs of osteonecrosis include:

- stiffness in the joints
- aches and pains in the joints (especially in the hip, knee or shoulder)
- difficulty moving.

If you notice any of these symptoms:

→ **Tell your physician.**

Weight, blood lipid and blood glucose effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. These effects are partly linked to restored health and lifestyle, and sometimes to the HIV medicines themselves. Your physician will test for these changes.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from

the physician.

- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Do not store above 30°C.

Tivicay 10 mg film-coated tablets: store in the original package to protect from moisture. Keep the package tightly closed. Do not remove the desiccant. Do not swallow the desiccant.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient the medicine also contains -
D-mannitol (E421), microcrystalline cellulose, sodium starch glycolate, povidone K29/32, sodium stearyl fumarate, polyvinyl alcohol-partially hydrolyzed, titanium dioxide (E171), macrogol, talc and for 25 and 50 mg tablets, iron oxide yellow (E172).
- What the medicine looks like and the contents of the package -
Tivicay film-coated 10 mg tablets: are white, round, biconvex and marked with the code "SV 572" on one side and "10" on the other side. The bottle contains a desiccant to reduce moisture. Keep the desiccant in the bottle after opening; do not remove it. The tablets are provided in bottles containing 30 tablets.
Tivicay film-coated 25 mg tablets: are light yellow, round, biconvex and marked with the code "SV 572" on one side and "25" on the other side. The tablets are provided in bottles containing 30 tablets.
Tivicay film-coated 50 mg tablets: are yellow, round, biconvex and marked with the code "SV 572" on one side and "50" on the other side. The tablets are provided in bottles containing 30 tablets.
- The bottles are closed with a child-resistant cap.
- Opening instructions: to remove the cap, press down, while simultaneously twisting to the left (turning counterclockwise).
Closing instructions: place cap on top of open end and twist to the right (turning clockwise) until it locks.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: ViiV Healthcare UK Ltd., London, England.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Tivicay 10 mg - 160-06-35311
Tivicay 25 mg - 160-07-35312
Tivicay 50 mg - 151-40-33983

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